

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/554,409
Applicant : Hans Grönlund
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Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. 1.131

I, Hans Grönlund declare that:

1. I am the same Hans Grönlund named as an inventor of the invention described and claimed in the above-referenced patent application. I submit this application on behalf of myself and my co-inventor, Marianne van Hage.

2. In an Office Action dated November 16, 2009, the examiner of this application asserted that the claims of this application lack a special technical feature over the combined teachings of Vailes et al., *J. Allergy Clin. Immunol.* 110(5):757-762 (Nov. 2002) and George et al., *Protein Engineering* 15(11):871-879 (2003).

3. Attached hereto as Exhibit 1 are 13 pages photocopied from one of my laboratory notebooks. These

pages are provided to establish completion of our invention in Sweden, a WTO country, subsequent to December 31, 1995, and prior to November 27, 2002, the earliest possible effective date of the two papers referenced above. The photocopied pages are complete and accurate reproductions of my original laboratory notebook with the exception that the dates of the entries have been redacted.

4. The attached photocopied laboratory notebook pages show the following:

1st page: front of the notebook, identifying it as mine;

2nd page (page numbered 248909): assembly of Fel d 1 chain 1 using PCR;

3rd page (page numbered 248910): assembly of Fel d 1 chain 2 using PCR;

4th page (page numbered 248923): expression and purification of Fel d chain 1 and chain 2;

5th - 7th pages (unnumbered page, page numbered 248926 and page numbered 248927): test of the chains with cat allergic patients and ELISA RAST of chain 1 and chain 2 separately (the unnumbered page is a photocopy of the back of the notebook page numbered 248925; the front of that page is not relevant to this showing and so is not provided);

8th and 9th pages (unnumbered page and page numbered 248928): assembly of Fel d 1 (2+1) and Fel d 1 (1+2) by PCR (the unnumbered page is a photocopy of the back of page 248927). As described in the application, in the (2+1) construct the C-terminal of chain 2 is linked to the N-terminal of chain 1 and in the (1+2) construct the C-terminal of chain 1 is linked to the N-terminal of chain 2;

10th and 11th pages (unnumbered page and page numbered 248931): ligation of Fel d 1 (2+1) and (1+2) PCR fragments into a vector, transformation and sequencing (the unnumbered page is a photocopy of the back of the notebook page numbered 248930; the front of that page is not relevant to this showing and so is not provided here);

12th page (page numbered 248932): ligation of the Fel d (2+1) and (1+2) constructs into the expression strain BL21 PlysS; and

13th page (page numbered 248933): expression of the constructs by SDS PAGE.

Also enclosed As Exhibit 2 are copies of the order sheets for the primers purchased for the construction of the (2+1) and (1+2) polypeptides as described in the attached notebook pages. These orders were placed by Dr. Omid Rasool, working under my direction in the lab. Again, these copies are accurate copies of the original order sheets except that the dates on which the orders were placed have been redacted.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that I have been advised that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 35 U.S.C. § 1001 and that such willful false

statements may jeopardize the validity of the application or any patent issuing thereon.

Hans Grönlund

Date